dynamics, Molecular Modelization) & in vivo. demonstrate that this MFM reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions. A saccular aneurysm without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. In fusiform aneurysms the flow is laminated, the vortexes eliminated, eliminating the risk of rupture. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM preserves the collateral branches and increases the flow in them, allowing the possibility to cover any artery without compromising the flow.
Results: 8 RAAs (right: 5, left: 3) in 8 pts (male: 3) mean age 58 y. treated with MFM* 6 pts had atheromatous disease, 2 a fibromuscular dysplasia. One pt had a solitary kidney. All these pts had hypertension, 2 a severe coronary disease. 10 MFM(∅: 5 to 6 mm, length 30 to 60 mm) loaded in a 6 F sheath implanted by femoral approach through 8 F guiding catheter. These stents covered major renal branches without compromising the flow. Technical success: 100%. No complications. Immediately it appears an important reduction of the velocities inside the aneurismal sac. 6 to 36 month follow up will be presented. All aneurysms thrombosed with diameter reduction in some pts. The thrombosis could take several weeks depending on the importance of collateral branches. All the side branches remain patent.
Conclusions: The MFM* is a new technique which seems to be promising to treat renal aneurysms. Collateral branches can be covered without compromising the flow and risk of renal infarction. Larger study is ongoing.

TCT-154

The Multilayer Flow Modulator Stent For The Treatment Of Popliteal Aneurysm

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Background: Popliteal Artery Aneurysms (PA) are traditionally treated surgically. Endovascular procedures with implantation of stent grafts or covered stents have been proposed as an alternative to surgery. Results are encouraging but some problems remain (aneurysm rupture, endoleaks, collateral branch thrombosis. . .). We developed a new concept of stent, the Multilayer Flow Modulator (MFM) to treat aneurysms and try to avoid some drawbacks encountered with endografts.
Methods: This MFM is a 3 Dimensional braided tube made of several interconnected layers without any covering. Our earliest tests in vitro (theorical simulation, computerized Fluid dynamics, Molecular Modelization) and in vivo demonstrate that this MFM reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions. A saccular aneurysm without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels . . .).
Results: 5 PA were treated with the MFM (male: 5, mean age: 65 y.) 9 stents (Ø6 to 8 mm, length 40 to 120 mm) were implanted by percutaneous ipsilateral femoral approach through 8F sheath. Technical success in all patients. All aneurysm thrombosed. Mid-term follow up will be presented. No stent fracture. This MFM seems well indicated for this popliteal location.
Conclusions: A new concept of stent, the MFM is developed to treat aneurysm. It opens a new approach to treat peripheral aneurysms avoiding most of the complications encountered with current endovascular techniques. The results obtained seem promising. A larger study is ongoing.

TCT-155

A New Concept Of Stent: The Multilayer Flow Modulator. First Human Study In Peripheral And Visceral Aneurysms

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Background: Arterial aneurysms (An) are traditionally treated surgically, but more and more by interventional procedures with a high technical success rate, but some problems are not solved like protection of aneurysm rupture, endoleaks, stent thrombosis, collateral branch thrombosis. We developed a new concept of stent, the Multilayer Flow Modulator (MFM*) to treat An. and try to avoid some drawbacks encountered with endografts.
Methods: This MFM* is a 3 Dimensional braided tube made of several interconnected layers without any covering. Our earliest in vitro (theorical simulation), computerized Fluid dynamics, Molecular Modelization and in vivo tests demonstrated that this MFM* reduces the velocity in the aneurismal sac up to 90% by modifying the hemodynamic conditions. A saccular aneurysm without collateral branch will thrombose quickly. If a collateral branch is present the flow is directed towards this branch leading to shrinkage of the aneurysm. Animal experiments show excellent results. Moreover, as demonstrated in animal and human studies this MFM preserves the collateral branches allowing the possibility to cover any artery without compromising the flow (renal, digestive arteries, supra aortic vessels. . .).
Results: 39 peripheral An. (iliac:23, femoral:1, popliteal:5, renal:8, mesenteric:1, Subclavian : 1) were treated with the MFM* (male:30, mean age 62+/−8 y) (51 stents ∅ 5 to 14 mm; length 40 to 120 mm) were implanted to treat these aneurysms, by femoral approach (38 cases), brachial approach (1 case), Technical success in all patients. No complications. All An. thrombosed with diameter reduction in some pts. The thrombosis could take several weeks depending on the importance of collateral branches. 6 month to 36 month follow up will be presented and we will discuss the time needed to achieve exclusion of the An. All the side branches remained patent.
Conclusions: A new concept of stent, the MFM* (without any covering) is developed to treat An. It opens a new approach to treat peripheral An. avoiding most of the complications encountered with current endovascular techniques. The results obtained seem promising. A larger study is ongoing.

TCT-156

Renal Angioplasty And Stenting. Limitations. Role Of Embolic Protection Devices

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Background: Despite good immediate and long-term results, post procedural deterioration of the renal function (RF) may occur after Renal Artery Angioplasty and Stenting (RAAS) in 20-40% of the patients, which limits the immediate benefits of the technique. Atheroembolism seems to play an important role. We evaluate feasibility and safety of RAAS utilizing a distal protection device (DPD) to reduce the risk of atheroembolism and avoid deteriorations of the RF.
Methods: 161 RAAS performed under DPD in 141 hypertensive patients (M:97). Mean age: 64.9 ± 11.8 yrs with atherosclerotic renal artery stenosis (20 bilateral). 11 pts had solitary kidneys, 57 renal insufficiencies. We used occlusion balloon (n = 46) or filters (n = 115). We recently experimented and treated 12 patients with a new filter the Fibernet (Lumen Biomedical Plymouth MN) which can capture particles of 40μ without compromising the flow. Generated debris removed and analyzed. Blood pressure and serum creatinine levels followed. Techniques of RAAS under protection, limitations will be discussed.
Results: Immediate technical success: 100%. Visible debris aspirated with Percusurge from all patients. Mean particle number: 98.1 ± 60.00. Mean diameter: 201.2 ± 76μ (38-6206). With current filters debris were removed in 80% of the cases. With the Fibernet visible debris were removed in all cases. Mean debris surface area: 121mm^2. Mean number of particles 28-60μ : 2136 ± 776, >60μ. We observed one acute RF deterioration. Mean follow-up: 31.2 ± 16 months. Mean creatinine level remains constant during follow-up. At 6 months (121 patients) 89 patients stabilized, 31 with baseline renal insufficiency improved and we had only one RF deterioration (1%) in a patient with moderate renal insufficiency. At 2 years (97 patients) 69 stabilized, 24 improved and we only had 4 RF deterioration (5%).
Conclusions: This study demonstrates the feasibility and safety of DPD during renal interventions to protect against atheroembolism and seems to avoid RF deterioration after the procedure and in the long-term. Indications will be discussed. Improvements in DPD for renal stenting are mandatory. Randomized studies are awaited.

TCT-157

Increased Local Cytokine Production at Culprit Superficial Femoral Artery Plaques

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Background: Characterization of arterial cytokines taken directly from areas of culprit superficial femoral artery (SFA) stenosis has not been studied. We hypothesized that arterial cytokine concentrations would be greater at sites of culprit stenosis, implicating inflammatory mediators in progression of SFA disease.
Methods: Twenty patients with ≥50% angiographic stenosis of the SFA had blood drawn just proximal to the lesion and from a contralateral site free of significant disease. A microplate immunoassay was used to determine the concentrations of 42 distinct cytokines and growth factors. Univariate analysis was used to compare blood collected at the two sites. Interaction terms identified clinical factors potentially impacting cytokine concentrations.
Results: The concentrations of soluble CD40 ligand (CD40L; mean 212 and 177 pg/ml, p≤0.01) and tumor necrosis factor beta (TNF-B; mean 16.6 and 15.9 pg/ml, p≤0.03) were increased in areas of stenosis (Figure). Predictors of greater concentrations at sites of stenosis were bilateral ankle-brachial index ≤0.90 (p=0.04), claudication (p=0.03), no known peripheral arterial disease or non-healing ulcer (p<0.05), low leukocyte count (p=0.03) and Rutherford class (p=0.05), as well as lack of aspirin, clopidogrel or statin (p<0.05).

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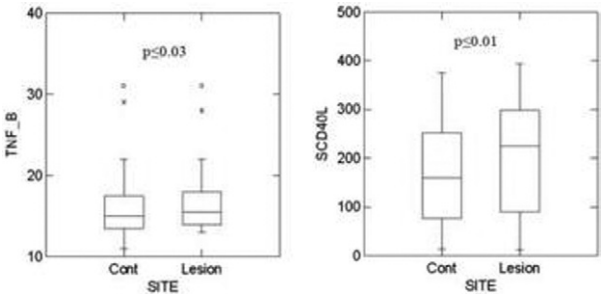

Conclusions: Greater concentrations of CD40L and TNF-B were seen at the site of stenosis and may promote inflammation in symptomatic SFA disease. A local inflammatory response is particularly notable in newly diagnosed, symptomatic patients not currently taking aspirin, clopidogrel or a statin.

TCT-158

Impact Of Subclinical Peripheral Arterial Disease Severity On Middle And Long Term Outcomes In Patients With ST-Elevation-Myocardial Infarction

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Background: The presence of clinical peripheral arterial disease (PAD) is associated with an increased risk of adverse cardiovascular outcomes among patients with coronary artery disease (CAD). However, there is little data regarding the impact of the presence and degree of the subclinical PAD on outcomes in patients with CAD, specially those that undergoing percutaneous coronary intervention (PCI) for ST-elevation-myocardial infarction (STEMI). We aimed to assess prospectively the grade of subclinical PAD in the setting of patients that undergoing primary PCI for prediction of middle and long-term clinical outcomes.
Methods: A total of 971 consecutive patients without history of clinical PDA that undergoing primary PCI for STEMI were included in a prospective follow-up. Subclinical PAD severity was blindly assessed based on a previously described ultrasound arterial morphology classification (UAMC) defined with an high-resolution ultrasound assessment of wall carotid and femoral artery bifurcations. This classification included four classes (I: normal, II: wall thickening, III: non-stenosing plaques, IV: stenosing plaques) corresponding to four scores ranging between 2 and 8 for each artery (total score from 8 to 32 in each patient. The group was divided into four classes according to UAMC and each patient was assigned a score. We evaluated death, and major cardiovascular and cerebrovascular events after 40 months'mean follow-up.
Results: At multivariable analysis, mortality in class IV group was more than 16-fold higher (hazard ratio [HR], 16.50; 95% confidence interval [CI], 7.76 to 35.07; P<0.001) when compared with the class I group and was also increased in the class III group (HR, 4.47; 95% CI, 2.55 to 8.76; P<0.001) and class II group (HR, 1.62; 95% CI, 1.30 to 2.18; P< 0.05). Similarly, an increasing effect was seen across UAMC strata for MACCE in the class IV group (HR, 12.29; 95% CI, 9.16 to 16.50; P<0.001), class III group (HR, 11.70; 95% CI, 8.54 to 16.24; P< 0.001), and class II group (HR, 1.92; 95% CI, 1.40 to 2.55; P=0.005).
Conclusions: The UAMC may be applied in the STEMI population that undergoing primary PCI and is able to stratify patients for poor middle and long term clinical outcomes.

TCT-159

Effects of PRT-201, a Recombinant Human Type I Pancreatic Elastase, Treatment on the Elastin Content and Compliance of Atherosclerotic Tibial Arteries Following Ex Vivo Angioplasty

Steven Burke[1], Emma Moss[2], Karen Macdonald[2], Marco Wong[3], Daniel Gottlieb[4], Kimberly Bland[3], F. Nicholas Franano[5]
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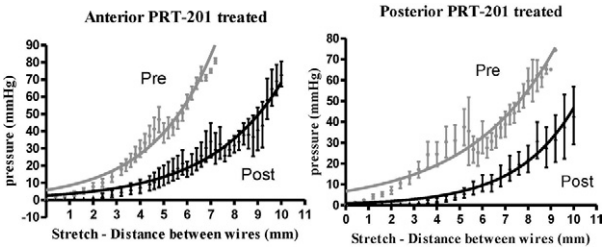
Background: At physiologic pressures, the elastin fiber network constrains artery diameter. Fragmenting elastin fibers following successful angioplasty of atherosclerotic arteries could result in larger artery lumen diameter and area. The purpose of this study was to investigate the use of PRT-201, a recombinant human type I pancreatic elastase, as an adjuvant therapy to balloon angioplasty for treatment of peripheral artery disease (PAD).
Methods: Diseased tibial arteries were harvested from patients undergoing lower limb amputations for PAD. Ex vivo balloon angioplasty was performed using a balloon chosen to match the lumen diameter of the artery taken at the intima-plaque interface. Thereafter, the arteries were cut into 6 x 1.5 mm rings and studied on a wire myograph to obtain baseline compliance data. Then the external surface of the artery was bathed in PRT-201 2 mg/mL or saline for 60 minutes and myography was repeated. Treated rings were analyzed for desmosine (elastin) content by RIA and elastin fiber staining by histology. Desmosine is a protein cross-link unique to elastin.
Results: PRT-201 but not saline caused a shift in the compliance curve of artery rings from the anterior and posterior tibial arteries (Figure) associated with an increases in lumen diameter and area across a range of pressures. PRT-201 treatment reduced desmosine (elastin) content by 60% and reduced elastin fiber staining on histology.
Conclusions: The results suggest that PRT-201 treatment following balloon angioplasty of atherosclerotic arteries could increase artery lumen diameter and area without requiring placement of a stent.



TCT-160

Effects of PRT-201, a Recombinant Human Type I Pancreatic Elastase, Treatment on the Elastin Content and Compliance of Atherosclerotic Tibial Arteries Using a Perfusion Myograph

Steven Burke[1], Karen Macdonald[2], Emma Moss[2], F. Nicholas Franano[3]
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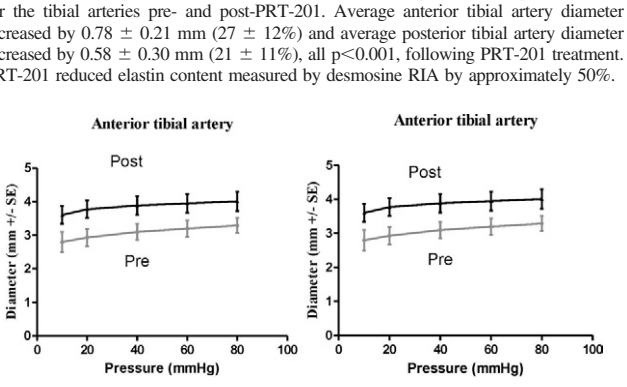
Background: At physiologic pressures, elastin fibers constrain artery diameter. Removing elastin fibers from an atherosclerotic artery could result in larger artery lumen diameter and greater blood flow. The purpose of this study was to investigate the use of PRT-201 as a treatment for peripheral artery disease (PAD).
Methods: Anterior and posterior tibial arteries were obtained within 24 hrs of death from persons who donated their bodies to science. The arteries were visually atherosclerotic. 3-4 cm long segments of artery were mounted onto the perfusion myograph and bathed in Krebs solution at 37C gassed with a mix of 95% O2/ 5% CO2. Transmural pressures were increased from 10 to 80 mmHg while diameter was continuously recorded to create a compliance curve. Then PRT-201 was applied at a concentration of 3.6 mg/mL for 30 min and the compliance curve was repeated. The artery was analyzed for elastin content by desmosine radioimmunoassay (RIA). Desmosine is a protein cross-link unique to elastin.
Results: 6 donors provided 10 tibial arteries. The figure displays the compliance curves for the tibial arteries pre- and post-PRT-201. Average anterior tibial artery diameter increased by 0.78 ± 0.21 mm (27 ± 12%) and average posterior tibial artery diameter increased by 0.58 ± 0.30 mm (21 ± 11%), all p<0.001, following PRT-201 treatment. PRT-201 reduced elastin content measured by desmosine RIA by approximately 50%.



Conclusions: PRT-201 treatment removed elastin from atherosclerotic tibial arteries and altered artery compliance so as to increase artery diameter.

TCT-161

Long term effect of transcatheter intra-arterial administration of bone marrow mononuclear cells in patients with critical limb ischemia

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Background: Therapeutic vasculogenesis in patient with critical limb ischemia (CLI) is an experimental method with good short term results. Successful vasculogenesis is achieved by transcatheter intra-arterial administration of autologous bone marrow mononuclear cells (BMMC) directly into the ischemic foot. However, the longterm effects of

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